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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,673	05/08/2001	Jonathan M.J. Derry	3198	3258

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/26/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/851,673	Applicant(s) DERRY ET AL.	
	Examin r Carolyn L Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

I. Claim 1, drawn to a method for identifying compounds that alter biological activities of CD40, classified in class 435, subclass 7.1. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

II. Claim 2, drawn to a method for identifying compounds that inhibit binding of NEMO and CYLD, classified in class 435, subclass 7.1. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

III. Claims 3-5, drawn to a method for producing information comprising the identity of compounds that alter biological activities of CD40 and alter NEMO/CYLD binding activity, classified in class 702, subclass 19.

IV. Claims 6-10, drawn to information produced in the method of claim 3, classified in class 211, subclass 41.12.

V. Claims 11-16, drawn to a computer system, classified in class 700, subclass 90. If this Group is elected then the below summarized sequence election is also required.

VI. Claim 17, drawn to a method of using a computer system to select compounds for testing, classified in class 702, subclass 19.

VII. Claims 18-20, drawn to a method of operating a computer system for analyzing compounds that modulate the interaction of NEMO and CYLD, classified in class 702, subclass 19.

VIII. Claim 21, drawn to a database, classified in class 211, subclass 41.12.

IX. Claim 22, drawn to a method of selecting compounds that alter biological activity of CD40, classified in class 702, subclass 19.

X. Claim 23, drawn to a method of increasing biological activities of CD40, classified in class 435, subclass 7.1.

XI. Claim 24, drawn to a method of decreasing biological activities of CD40, classified in class 435, subclass 7.1.

Sequence Election Requirement Applicable to Groups I, II, and V:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequences, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP § 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR § 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Specie Election Requirement for Groups I and II:

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Groups I and II:

Specie A: method for identifying compounds which are antibodies

Specie B: method for identifying compounds which are non-antibodies

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims in Group I and II are generic to the above species. This distinctness or independence of an antibody versus non-antibody is described below.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings I, II, III-XI, I (antibody specie), I (non-antibody specie), II (antibody specie), and II (non-antibody specie) are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Group I, the critical feature is a CD40. For Group II, the critical features are

NEMO and CYLD. For Groups III-XI, the critical feature is a database. For Group I (antibody specie), the critical feature is an antibody that alters biological activity of CD40. For Group I (non-antibody specie), the critical feature is a non-antibody that alters biological activity of CD40. For Group II (antibody specie), the critical feature is an antibody that inhibits binding of NEMO and CYLD. For Group II (non-antibody specie), the critical feature is a non-antibody that inhibits binding of NEMO and CYLD. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the seven Groupings I, II, III-XI, I (antibody specie), I (non-antibody specie), II (antibody specie), and II (non-antibody specie) are independent and/or distinct invention types for restriction purposes.

Inventions in Groups III-XI are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case database of Group VIII may be utilized in distinct usages as needed in Group III for a method of producing information comprising the identity of compounds, in the information produced as in

Group IV, in a computer system as in Group V, in a method of using a computer system to select compounds for testing as in Group VI, in a method operating a computer system for analyzing compounds as in Group VII, in a method of selecting compounds that alter biological activity of CD40 as in Group IX, in a method of increasing biological activities of CD40 as in Group X, in a method of decreasing biological activities of CD40 as in Group XI, or alternatively, in storing other biological data. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO

Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 9 A.M. to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 23, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER